Paper Dated: November 25, 2009

In Reply to USPTO Correspondence of August 31, 2009

Attorney Docket No. 0470-051057

REMARKS

The Office Action of August 31, 2009 has been reviewed and the Examiner's comments have been carefully considered. Claims 17-31 are pending in the present application, and claim 17 is in independent form.

35 U.S.C. §103(a) Rejections

Claims 17-31 remain rejected under 35 U.S.C §103(a) for asserted obviousness over WO 98/32336 to Livermore (hereinafter, "Livermore") in view of WO 99/08553 to Kringelum (hereinafter, "Kringelum"). Essentially, as outlined on pages 3-5 of the Office Action, the Examiner asserts that one of ordinary skill in the art would be able to take the combined teachings of Livermore and Kringelum in order to arrive at the subject matter set forth in claims 17-31. The Applicants respectfully disagree with the Examiner.

As reiterated by the Supreme Court in KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 82 U.S.P.Q.2d 1385 (2007), the framework for the objective analysis for determining obviousness under 35 U.S.C. §103 is stated in Graham v. John Deere. Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc., 72 Fed. Reg., No. 195 (October 10, 2007) at page 57527 (hereinafter "Examination Guidelines"). The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
- (2) Ascertaining the differences between the claimed invention and the prior art; and
- (3) Resolving the level of ordinary skill in the pertinent art.

Examination Guidelines at page 57527.

"The ultimate determination of patentability must be based on consideration of the entire record, by a preponderance of evidence, with due consideration to the persuasiveness of any arguments and any secondary evidence." <u>Manual of Patent Examining Procedure</u>, (Sept. 2007) §716.01(d) and *In re Oetiker*, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

Livermore teaches a bread improver comprising a latent enzyme preparation which is active during or after proving, but relatively inactive during mixing. Example 1 of Livermore describes the preparation of a granulate by coating an α-amylase agglomerate (having

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an average particle size of around 150 microns) with a fat having a slip melting point of about 35°C.

On page 5, lines 27-29, of Livermore the following eight different enzyme encapsulants are mentioned: (a) fat, (b) gelatin, (c) gum (e.g. vegetable gum), (d) maltodextrin, (e) starch (e.g. modified starch), (f) emulsifiers, (g) waxes, and (h) sugars. Livermore, however, fails to teach an encapsulating layer containing 50-98 wt.% of a triglyceride fat and 2-50 wt.% of a release agent selected from the group of monoglycerides, diglycerides, diacetyl tartaric acid ester of mono- and/or diglyceride (datem), stearyl-lactylates and combinations thereof.

Kringelum teaches encapsulation of a wide range of food additives using, for example, edible fatty substances as encapsulating components (page 12, lines 10-11). Kringelum further teaches to employ the following as edible fatty components: monoglycerides, diglycerides, mono/diglycerides, trigycerides or mixtures thereof (page 12, lines 13-15). However, just like Livermore, Kringelum does not teach a granulate that comprises an encapsulating layer containing 50-98 wt.% triglyceride fat and 2-50 wt.% of a release agent as specified in claim 17 of the present application.

According to the Examiner at page 6, paragraph 5, of the Office Action:

The combination of encapsulating materials taught in Livermore and Kringelum produces results that would have been obvious to a person of ordinary skill in the art. The encapsulating materials taught by Kringelum are well known emulsifiers. The person of ordinary skill in the art would have appreciated that an encapsulating layer comprising fat and an emulsifier would in fact create an emulsion with the fat and with moisture found in dough. Thus, the presence of the emulsifier in the encapsulating layer would promote the breakdown of the fat in the presence of water which is present during the mixing phase of bread making.

The Examiner further states at page 6, paragraph 6, of the Office Action:

Additionally, Livermore specifically teaches that the enzyme may be released by an attritional agent such as a surfactant (equivalent to an emulsifier) (Page 6, Line 30). Livermore teaches that in preferred embodiments the attritional agent is an inherent property of the dough which, in fact, suggests that the attritional agent in less preferred embodiments may be found in ways that are not inherent to the dough. As mentioned above, it is prima facie

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obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. Therefore, it would have been obvious to a person of ordinary skill in the art to have combined the encapsulants of Livermore and Kringelum and thus provide the attritional agent (emulsifier/surfactant) in the encapsulating layer.

However, as explained previously, neither Livermore nor Kringelum teaches a granulate that contains an encapsulating layer containing 50-98 wt.% of a triglyceride fat and 2-50 wt.% of a release agent selected from a group of monoglycerides, diglycerides, diacetyl tartaric acid ester of mono- and/or diglyceride (datem), stearyl-lactylates and combinations thereof.

In the Applicants' view, at the time of the present invention, a person of ordinary skill in the art would not have been motivated to modify the granulates taught by Livermore or Kringelum by employing therein an encapsulating layer that contains 50-98 wt.% of a triglyceride fat and 2-50 wt.% of a release agent (emulsifier). For the reasons presented below, the Applicants respectfully disagree with the Examiner that the statements in Livermore concerning attritional agents would have provided such motivation. In addition, the Applicants refer to the attached Expert's Declaration by Dr. Udo Scharf (hereinafter, "the Expert's Declaration") which supports the view that the latter statements would not have motivated a person of ordinary skill to incorporate a release agent as defined in present claim 17 in a fat-coated enzyme encapsulate.

As discussed in paragraph 3 of the Expert's Declaration, in the latter passage of Livermore, it is explained that in a preferred embodiment, the enzyme contained in the latent enzyme preparation is released during or after proving by: (i) temperature-mediated release (i.e. thermal breakdown of an encapsulant); (ii) water-mediated release; or (iii) an attritional agent (e.g. an enzyme, surfactant or acidulant).

As stated in paragraph 4 of the Expert's Declaration, the term "attritional agent" is defined in Livermore as any agent (for example, a chemical moiety, an enzyme, or a particular physical condition or treatment) which breaks down a barrier between the enzyme and the dough to release the enzyme. It is stated that the attritional agent preferably is an inherent property of

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the dough during or after proving, such as its temperature or moisture level. Livermore additionally provides the following examples of suitable combinations of encapsulants and attritional agents:

Encapsulant	Attritional agent
Fat	Temperature differential
Starch	Water
Pectin gum	Pectinase
Other gums (guar, xanthan etc.)	Degradative enzyme

In paragraph 5 of the Expert's Declaration, Dr. Scharf concludes that Livermore teaches latent enzyme preparations in the form of enzyme encapsulants that contain fat as an encapsulant. Furthermore, Livermore mentions surfactant as a potential attritional agent. However, Livermore does not provide any explanation as to the type of latent enzyme preparation in which a surfactant may be used as an attritional agent, the type of surfactant that might be used, the way it should be employed or the mode of its action.

In paragraph 6 of the Expert's Declaration, Dr. Scharf states that it is his professional view that Livermore would not have motivated a person of ordinary skill in the art to include a surfactant as an attritional agent in a fat-based encapsulant of a latent enzyme preparation, especially not if said surfactant is a release agent as defined in claim 17 of the above referenced patent application. Dr. Scharf's view is based on the following observations:

- (i) Livermore does not mention the possibility of incorporating an attritional agent into a latent enzyme preparation. Instead, the practical examples of attritional agents provided by Livermore are either a physical condition (temperature differential) or are components (water, enzymes, surfactants {≈emulsifiers}) that are normally present in the dough.
- (ii) Livermore expressly teaches that the enzyme should not be released prior to proving (see, for instance, page 2, lines 21-24 and page 6, lines 34-36). If an attritional agent (enzyme, surfactant, acidulant) is incorporated into an enzyme encapsulate, a person skilled in the art would expect release of the encapsulated enzyme to occur as soon as the encapsulate comes into contact with moisture, i.e. early on during the dough mixing stage. This is

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because the attritional agent is present in relatively high concentration in and around the encapsulate particles. Instead, if the attritional agent is present in the dough, its releasing action will be much less pronounced as in that case the attritional agent is homogeneously distributed throughout the dough. A person of ordinary skill in the art would expect a surfactant that is homogeneously distributed throughout a dough to exert its destabilizing effect once the fat coating starts to melt during proving or baking.

(iii) The release agents mentioned in claim 17 of the above captioned patent application are commonly employed as emulsifiers in bread dough. In other words, bread dough more often than not contains such emulsifiers. If it is assumed that the term "surfactant" as used by Livermore encompasses the latter emulsifiers, it is my view that a person of ordinary skill trying to deduce how a surfactant might act as an attritional agent in accordance with the teachings of Livermore would reach the conclusion that emulsifiers (surfactants) as present in bread dough may act as an attritional agent. Said skilled person would not deduce from Livermore that the aforementioned emulsifiers, in order to act as an attritional agent, should be incorporated in an encapsulate as part of the encapsulant.

In paragraph 7 of the Expert's Declaration, Dr. Scharf states that it is his view that a person of ordinary skill in the bakery art might be motivated by Livermore to employ surfactants (emulsifiers) that are commonly used in dough as attritional agents that will assist in breaking down the fat barrier between fat-encapsulated enzyme and the dough once the fat starts to melt during proving or baking. However, said skilled person would not be incited by Livermore to include such surfactants in the encapsulant of fat encapsulated enzyme as this person would expect such inclusion to cause rapid release of the enzyme early on during the dough mixing stage. Clearly, the release of enzyme activity during the dough mixing stage goes exactly against the teaching of Livermore to provide a latent enzyme system that only starts releasing the enzyme during or after proving.

At page 6, lines 32-36 of Livermore, it is explained that an attritional agent breaks down a barrier between the enzyme and the dough to release the enzyme and that, preferably, the attritional agent is an inherent property of the dough during or after proving, such as its temperature or moisture level. In the first paragraph of page 7 of Livermore, Livermore further

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states that where the encapsulant is fat, "the attritional agent is primarily the temperature differential between the mixing and post-mixing steps: the relatively high temperatures at the proving stage effectively melt the fat capsule and release the enzyme".

Thus, Livermore explicitly teaches that in the case of fat, the temperature differential between the mixing and post-mixing steps is the primary attritional agent. No teaching or suggestion can be found in Livermore that an emulsifier can suitably be used as an attritional agent for a fat coated enzyme preparation, or that Livermore suggests to incorporate such an emulsifier in the encapsulant, or, more particularly, to incorporate it therein in a concentration of 2-50% by weight of encapsulant.

A crucial element of the enzyme-based bread improvers, according to Livermore, is the use of an encapsulant to ensure that the enzyme is active during and after proving, but relatively inactive during mixing (see claim 1 and Examples). In accordance with this basic teaching (see page 6, lines 34-36 of Livermore), an attritional agent should exert its attritional effect during or after proving, i.e., not before proving. As explained by Dr. Udo Scharf at paragraph 6 (ii) in the attached Expert's Declaration, a person of ordinary skill in the art would expect a surfactant that is homogeneously distributed throughout a dough to exert its destabilizing effect once the fat coating starts to melt during proving or baking. In contrast, said skilled person would expect inclusion of appreciable levels of surfactant in a fat-based encapsulant to result in almost instant destabilization of the encapsulant as soon as the encapsulant comes into contact with water, i.e., during dough mixing. Clearly, in the context of the teachings of Livermore, such a fast release prior to proving is undesirable.

Unexpectedly, the Applicants of the present invention have found that inclusion in a fat-based encapsulant of 2-50 wt.% of a release agent as defined in claim 17 does trigger release of the encapsulated material when it comes into contact with water at sub-proving temperature, but this release was found to be gradual rather than instant. This gradual release offers significant advantages as explained and illustrated in the present application.

In the second paragraph of the Summary of the Invention of the present application, it is observed:

As compared to the coated and encapsulated systems known from the prior art, the present granules offer the advantage that the

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functionality is generally released in a more gradual way, allowing the functional ingredient to already exert some of its functionality early on during the dough preparation process. In case of enzymes, for instance, such an early controlled action is desired to produce a baked product with good consistency and volume. Thus, the invention enables the preparation of a dough that is easy to handle and that yields a baked product with excellent consistency and volume.

The Examples of the present application indeed show that the rate at which the encapsulates of the present invention release encapsulated enzymes in the presence of water increases gradually with temperature, whereas encapsulates that comprise a purely fat-based encapsulant show a much slower release (see Example 2). Example 3 of the present application clearly demonstrates that, as a result of the gradual release of enzyme activity at lower temperatures, the granules of the present invention outperform granules that comprise 100% fat-encapsulated enzymes in that they have a less dry and stiff consistency as well as a significantly higher specific volume. Applicants assert that a person of ordinary skill in the art who is familiar with the teachings of Livermore and Kringelum would not have foreseen the latter advantages and, as such, the present invention achieves unexpected results.

Kringelum broadly teaches to employ a coating layer that comprises monoglycerides, diglycerides, mono/diglycerides, trigycerides and esters of mono- and diglycerides with organic acids to prevent undesirable interactions between an encapsulated food additive and other components of a food system during part of the processing of such systems (page 2, lines 19-23). However, Kringelum fails to cure the deficient teachings of Livermore.

It can be concluded that the teachings of Livermore have more in common with the present invention than the teachings of Kringelum. Whereas Livermore, like the present invention, is concerned with delaying the action of a functional bakery ingredient, such as an enzyme, during dough preparation until the proving stage, Kringelum does not even mention proving (except in Examples 2 and 3). Furthermore, whereas Livermore is concerned with enzyme encapsulates, Kringelum is primarily concerned with the encapsulation of a preserving agent, notably calcium propionate (see Examples 1-3).

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Thus, Applicants fail to appreciate how, at the time of the present invention, Kringelum would have incited a person skilled in the art to partly replace the triglycerides in the coating of the latent enzyme preparations of Livermore by an emulsifier. In addition, there is no teaching or suggestion that one of ordinary skill in the art would have held a reasonable expectation that such partial replacement would improve the functionality of said latent enzyme preparations.

In light of the foregoing, Applicants assert that one of ordinary skill in the art, at the time of the present invention, would not have been able to combine the teachings of the cited references in order to arrive at the subject matter of the claimed invention. Withdrawal of the rejection and allowance of independent claim 17 are respectfully requested. Claims 18-31 depend from, and add further limitations to claim 17. Therefore, Applicants submit that all of depending claims 18-31 should also be in condition for allowance.

Respectfully submitted,

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